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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 10/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,957

Applicant(s)

NYCZ ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-20 is/are rejected.
- 7) ☒ Claim(s) 1 and 20 is/are objected to.
- 8) ☒ Claim(s) 8 and 9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION***Election/Restrictions***

Applicants' election without traverse of the invention of Group I defined by claims 1-7 and 10-20 in Paper No. 6, filed on July 14, 2003 is noted. Accordingly, this Office Action addresses only claims 1-7 and 10-20.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference element mentioned in the description: porous coating 76 (page 12, para 1, line 6) is not shown in the drawings. Although, Applicants indicated submission of revised Figure 1 in Paper No. 6; a revised Figure 1 was not attached to Paper No. 6. A proposed drawing correction or corrected drawings are required in reply to this Office Action to avoid abandonment of the application.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 1, 10, 15 and 20. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required. The specification must be amended to include the subject matter, "a wall and a bottom defining a recess" introduced by amendment in claims 1, 10 and 20 and "a first wall and a first bottom defining a first recess," and a "second wall and a second bottom defining a second recess" introduced by amendment in claim 15.

Claim Objections

Claims 1 and 20 are objected to because they recite "a substantially planar surface extending over substantially all of the bottom," in addition to the bottom that would not appear to be the case in the disclosed invention. Appropriate correction is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 7, 15, 18, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (US 5,370,702).

Regarding claims 1, 4, 6, 15 and 19, Jones discloses an implant or prosthesis or cup 10 having a convex surface 20 and a concave surface 18. Recesses 14 are provided in the inner surface 18; each recess having a sidewall 22 and a planar base 27 with a removable portion 24 about 0.005 inches thick. Jones further discloses that punching may be applied to remove portion 24 to form a hole in cup 10; the hole being used to fasten cup 10 by a bone screw or other fastener (col. 1, lines 7-10; col. 2, lines 14-38 and line 68; col. 3, lines 1-3, lines 13-19, lines 22-23, lines 37-49 and lines 57-64; col. 4, lines 15-18, lines 35-37 and lines 43-47; and Figures 1 and 3).

Regarding claim 2, with regard to the reduced thickness portion being “adapted to block the flow of synovial fluid therethrough,” it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 7 and 18, with regard to the reduced thickness portion being “adapted to be sheared by a punch tool,” it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

The method steps of claim 20 are inherently performed during normal use of the prosthesis or cup 10 of Jones for the purpose of replacement of the acetabulum or hip socket due to bone disease or severe fracture (col. 1, lines 13-15).

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Claims 1-7, 15 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Miser (WO 95/15734).

Regarding claims 1, 4, 6, 15 and 19, Miser discloses an implant or prosthesis or cup 10 having a convex surface 12 and a concave surface 14. Screw holes or "recesses" 50 are provided with each recess having a sidewall 52 and a planar base 56 with a seal or removable portion 62 about 0.025 to 0.010 inches thick. Miser further discloses that punching may be applied to remove portion 62 to form a hole in cup 10; the holes being used to fasten cup 10 by bone screws (Pages 4-7 and Figures 1-3).

Regarding claim 2, with regard to the reduced thickness portion being "adapted to block the flow of synovial fluid therethrough," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 3, Miser discloses that removable portion 62 is placed in a recess having a generally cylindrical shape (page 5, lines 16-18).

Regarding claims 5 and 17, Miser discloses that a total hip prosthesis has a femoral component with a stem and a head integral with or removably attached to the stem and an acetabular component or cup with a bearing insert or liner for receipt of the head of the femoral component (Page 1, lines 6-26).

Regarding claim 7 and 18, with regard to the reduced thickness portion being "adapted to be sheared by a punch tool," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

The method steps of claim 20 are inherently performed during normal use of the prosthesis or cup 10 of Miser for the purpose of replacement of the acetabulum or hip socket of a diseased or damaged hip joint (page 1, lines 6-15).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 10-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones.

Regarding claims 3, 10, 12 and 16, Jones does not specifically disclose that removable portion 24 is in a recess having a cylindrical or a constant cross section.

Jones states that sidewall 22 of recess 14 housing removable portion 24 can have a shape, other than frustoconical depending on the configuration of the fastener used (col. 3, lines 44-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a recess having a constant cross section, as taught by Jones, to accommodate a suitably shaped fastener. Further, it would have been obvious to one of ordinary skill in the art to have provided a recess with a constant cross section since it has been held that mere changes in shape are a matter of obvious design choice absent any persuasive evidence that the particular shape or configuration is significant. *In re Dailey*, 149 USPQ 47 (CCPA 1976).

Regarding claim 11, with regard to the reduced thickness portion being "adapted to block the flow of synovial fluid therethrough," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 13, see discussion for claim 4.

Regarding claim 14, with regard to the reduced thickness portion being "adapted to be sheared by a punch tool," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

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Regarding claims 5 and 17, Jones discloses that acetabular cups typically include a liner into which the femoral head fits (col. 1, lines 13-23). It is well known that a femoral head is supported by and operably connected to a stem.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a stem, a femoral head operably connected thereto and a liner positioned between the acetabular cup and the femoral head for replacement of the hip socket.

Claims 10-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miser in view of Jones.

Regarding claims 10-14 and 16, Miser does not specifically disclose that removable portion 62 is in a recess or void having a cylindrical or a constant cross section.

Jones states that sidewall 22 of recess 14 housing a removable portion can have a shape, other than frustoconical depending on the configuration of the fastener used (col. 3, lines 44-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a recess having a cylindrical or a constant cross section, as taught by Jones, in the cup of Miser, to accommodate a suitably shaped fastener. Further, it would have been obvious to one of ordinary skill in the art to have provided a recess with a constant cross section since it has been held that mere changes in shape are a matter of obvious design choice absent any persuasive evidence that the particular shape or configuration is significant. *In re Dailey*, 149 USPQ 47 (CCPA 1976).

Regarding claim 11, with regard to the reduced thickness portion being "adapted to block the flow of synovial fluid therethrough," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Regarding claim 13, see discussion for claim 4.

Regarding claim 14, with regard to the reduced thickness portion being "adapted to be sheared by a punch tool," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

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Response to Arguments

Applicants' arguments filed in Paper No. 6 with respect to claims 1-7 and 10-20 have been fully considered but are not persuasive.

Applicants' arguments are fully addressed in the rejections and objections made in this Office Action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anu Ramana*
October 3, 2003


EDUARDO C. ROBERT
PRIMARY EXAMINER